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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,939	12/29/2000	Bruce L. Gibbins	01005-0121 (41946-251368)	9231
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Mary Anthony Merchant Ph D Trouman Sanders LLP Bank of America Plaza 600 Peachtree Street NE Suite 5200 Atlanta, GA 30308-2216				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/752,939

Applicant(s)

GIBBINS ET AL.

Examiner

Isis A. Ghali

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 6, 8, 21-28, 31-35 and 38-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 8, 21-28, 31-35, 38-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-543)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment a filed 05/05/2008.

Claims 3, 5, 7, 9-20, 29, 30, 36, and 37 have been canceled.

Claims 40-71 have been added.

Claims 1, 2, 4, 6, 8, 21-28, 31-35, 38-71 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 1, 2, 4, 6, 8, 21-28, 31-35, 38-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0042587 ('587) in view of US 5,792,090 ('090).

The present claim 1 is directed to a product comprises matrix of cross-linked polyacrylamide polymer containing oxygen.

US '587 teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam that can be produced chemically and contains gasses including oxygen (paragraph 0036).

However, US '587 does not teach the chemical reaction that produces the gas in the foam as claimed in claim 1. US '587 does not teach polyacrylamide polymer as claimed in claims 3 and 37.

US '090 teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises hydrogel or polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs

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hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The hydrogel or foam can be guar gum or polyacrylamide and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam that can be produced chemically as disclosed by US '587, and produce the foam by oxygen gas delivered by the reaction of hydrogen peroxide and catalyst and replace the polymer by polyacrylamide as disclosed by US '090, motivated by the teaching of US '090 that such polyacrylamide polymer foam containing oxygen are optimal for minimization of infection, with reasonable expectation of having polyacrylamide cross-linked closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin.

Response to Arguments

10. Applicant's arguments filed 05/05/2008 have been fully considered but they are not persuasive.

Applicants argue that US '587 does not teach foaming cross-linked polymeric network and reaches formation of foam by stirring a polymer solution with high speed or by gas injection. Therefore, the gas is introduced into the composition when the polymer solution is a liquid and before the polymer solution is cross-linked.

In response to this argument, applicants' attention is drawn to the scope of the present claims that is directed to a product comprising cross-linked matrix containing

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oxygen in closed cells. US '587 teaches polymeric cross-linked foam reservoir comprising cross-linked polymer and closed cell containing oxygen that can be produced chemically. US '587 suggests chemical formation of gas in the closed cells. Regarding product by process claims, it has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Cross linking of the polymer matrix before or after addition of oxygen does not impart patentability to the claims because it has been held that it is prima facie obvious to reverse the order of the prior art process steps, *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690,69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), selection of any order of mixing ingredients is prima facie obvious. Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix. Additionally, regarding the order of steps, it is argued that US '587 teaches product comprising oxygen within the cross-linked matrix, and US '090 teaches the use of cross-linked polyacrylamide and the chemical reaction that produces the oxygen, therefore, the combination of the references would teach cross-linked polyacrylamide matrix comprising closed cells

containing oxygen. The invention as a whole is taught by the combination of the references.

Applicants further argue that there is no suggestion or motivation to make the proposed modification of the polyacrylamide of the US '090 in the foam of US '587, and replacement of the polymer of US '587 with polyacrylamide of the '090 would altered the entire teachings of US '587 and renders the matrix of US '587 unsatisfactory to its intended purpose and a gelatinous mass may result and polyacrylamide would not cross-link.

In response to this argument, it is argue that US '090 teaches method for chemical generation of oxygen using catalyst and peroxide that is suitable for wound dressings and also teaches polyacrylamide matrix containing the oxygen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace cross-linked polymer with polyacrylamide and generate oxygen into the wound dressing disclosed by US '587 using catalyst and peroxide as used by US '090 because US '090 teaches polyacrylamide matrix comprising oxygen reduced infection, with reasonable expectation of having cross-linked polyacrylamide matrix containing closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin. The invention as a whole is taught by the combination of US '587 and US '090. An article comprising cross-linked polyacrylamide matrix and oxygen in closed cells as claimed would have been obvious to one skilled in the art at the time the invention was made

because the prior art recognized cross-linked polymeric matrix containing oxygen in closed cell delivered chemically and also recognized the suitability of polyacrylamide and the oxygen generation from reaction off catalyst and peroxide in wound dressing. It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Applicants argue that US '587 does not teach transfer of oxygen from the matrix and its delivery.

In response to this argument that, it is argued that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. US '587 is directed to wound treatment as intended by the present invention.

Applicants argue that US '090 does not cure the deficiencies of US '587 as it teaches occlusive dressing not capable for delivering oxygen, and teaches reservoir or

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sponge or open cell foam. The combination of the references would not result into the present invention.

In response to this argument, it is argued that US '090 is relied upon for the solely teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide. The cross-linked polymer matrix is taught by US '587, but US '587 does not specifically teach polyacrylamide. Further, US '090 teaches advantage of dressing comprising polyacrylamide polymer and oxygen generated from the reaction of catalyst and peroxide to supply oxygen to the wound for optimal healing and minimization of infection, and this would have been motivated one having ordinary skill in the art at the time of the invention to replace the polymer matrix disclosed by US '587 with polyacrylamide matrix and create oxygen by the reaction of catalyst and peroxide as disclosed by US '090. The present language of the claims does not exclude the presence of occlusive layer, and US '090 teaches delivery of oxygen and does not teach that the occlusive layer to prevent the oxygen delivery, but to prevent escape of oxygen from the device to the atmosphere.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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